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The economics of new product launches and access to pharmaceutical products in the EU: A perspective on the EC's proposed reform of the EU pharmaceutical legislation

ABSTRACT

One goal of the European Commission's proposed reform to existing regulations is to increase patient access to innovative medicines across the European Union. We describe the economic impact of this policy change. Because of the incentives created by other policies, particularly external reference pricing and parallel trade, these reforms may have an adverse impact on competition in the pharmaceutical sector and reduce the attractiveness of Europe as an incubator for pharmaceutical innovation. Changes to bargaining power are likely to favour large, established firms. These reforms also increase the uncertainty of the length of market exclusivity, potentially undermining innovation incentives.

L'un des objectifs de la réforme des réglementations existantes proposée par la Commission européenne est d'améliorer l'accès des patients aux médicaments innovants dans toute l'Union européenne. Nous décrivons l'impact économique de ce changement de politique. En raison des incitations créées par d'autres politiques, en particulier celles relatives aux prix de référence externes et au commerce parallèle, ces réformes peuvent avoir un impact négatif sur la concurrence dans le secteur pharmaceutique et réduire l'attrait de l'Europe en tant qu'incubateur de l'innovation pharmaceutique. L'évolution des rapports de force est susceptible de favoriser les grandes entreprises établies. Ces réformes augmentent également l'incertitude quant à la durée de l'exclusivité commerciale, ce qui pourrait nuire aux incitations à l'innovation.

The views expressed herein are those of the authors and do not necessarily represent the views of Cornerstone Research.

I. Introduction

1. On 26 April 2023, the European Commission (EC) adopted a proposal to reform existing regulations as part of its Pharmaceutical Strategy for Europe.[1] The EC's proposed reform encompasses several objectives,[2] one of which is improving patients' access to innovative medicines across the European Union (EU).[3] To this end, the EC aims to ensure that authorized medicines are launched promptly in all EU Member States and that patients across the EU have access to innovative medicines.[4]

2. In this paper, we describe the economic implications of this policy change. To evaluate the EC's proposed policy for increasing access, we believe it is helpful to understand better factors causing staggered launches and reduced access in the current regulatory environment. In this paper, we discuss two such factors: external reference pricing (ERP) and parallel trade. As we describe below, these factors have not been properly assessed in prior evaluations of the proposal.[5]

1 Eur. Comm., Reform of the EU pharmaceutical legislation, 26 April 2003, https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en; Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Reform of the pharmaceutical legislation and measures addressing antimicrobial resistance, COM(2023) 190 final, 26 April 2023 ("EC Communication"), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023DC0190&qid=1682665765572; Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Pharmaceutical Strategy for Europe, COM(2020) 761 final, 25 November 2020, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0761.

2 Other objectives of the proposed reform include (i) addressing the issue of increasing antimicrobial resistance; (ii) ensuring and improving the environmental sustainability of medicines; (iii) improving the attractiveness, competitiveness, of the EU pharmaceutical industry; (iv) fostering innovation, and research and development in the EU. *See* EC Communication, p. 1.

3 Ibid., pp. 1–2.

4 Eur. Comm., Study in support of the evaluation and impact assessment of the EU general pharmaceuticals legislation, Impact Assessment Report, Written by Technopolis Group for the Directorate General for Health and Food Safety, June 2022 ("EC Impact Assessment Report"), pp. 18–19.

5 For example, the EC's impact assessment incorrectly assumes there would be no effect on the revenue of originator firms that launch in all markets. Specifically, the EC assumes that "*the cost of servicing say 25 EU markets on average rather than say 15* (…) *would be cost neutral, with the higher sales volumes in the additional 10 smaller markets offsetting the additional marketing, distribution and other costs associated with smaller / marginal markets*." EC Impact Assessment Report, p. 173, C.4.3.

3. Below, we explain that the proposed policy will likely impact competition and innovation in the EU pharmaceutical market. More specifically, the proposal may:

- Reduce the returns to innovation for a significant number of manufacturers, which in turn would reduce competition among branded pharmaceutical products in the long run.
- Increase the bargaining power of large incumbent firms relative to smaller innovators, particularly in licensing agreements.
- Increase the bargaining power of small countries in pricing and reimbursement negotiations, thereby increasing the uncertainty of returns to innovation.

4. Jointly, these effects may have an adverse impact on competition in the pharmaceutical sector and reduce the attractiveness of Europe as an incubator for pharmaceutical innovation.

II. The European Commission's proposal to improve access to medicines across Member States

5. The EC plans to improve patients' access to medicines by changing the length of market exclusivity granted to manufacturers of new pharmaceutical products (i.e., originators) in the EU and the conditions under which exclusivity is granted. Currently, originators are granted ten years of exclusivity (through eight years of regulatory data protection and two years of market exclusivity) starting from the date of marketing authorization in the EU.[6] During this period, originators are the sole source of the new pharmaceutical product in the EU, as generic manufacturers are not allowed to enter the market.

6. Like patent protection, market exclusivity incentivizes innovation by increasing the expected returns from innovative products.[7] As the exclusivity period protects the originator from competition, the originator receives higher profits, which allows the recovery of sunk costs involved in research and development (R&D).[8] A large body of work confirms that innovative efforts are increasing in expected revenues, which generally are higher for an originator protected from competition.[9] In addition, ample evidence suggests that drug development efforts respond to changes in expected exclusivity periods.[10] This response varies across specific policies,[11] with unintended effects triggering further legal reforms.[12] Consequently, any policy that affects expected revenues and exclusivity has implications for innovation.

7. The proposed policy would change the length and terms of market exclusivity as follows:

- Baseline exclusivity will be reduced to eight years: six years of data exclusivity and two years of market exclusivity.
- If the product launches in all Member States, the exclusivity will be extended by two additional years.

8. There is uncertainty about how the "launch in all Member States" criterion would be applied in practice. To apply for the extended exclusivity period, the applicant must prove that the product has been released and is continually supplied in "*sufficient quantity*," in all Member States.[13]

9. To benefit from the additional exclusivity, manufacturers must (i) fulfil the requirement within two years of initial market authorization, and (ii) submit their application for additional exclusivity within three

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6 EC Communication, p. 8.

7 Regulatory market exclusivity differs from patent protection in two important ways. While market exclusivity terms begin at the date of approval, the twenty-year patent term begins from the date the patent is filed, which is typically early in a drug's development. Thus, there is uncertainty over how much of the patent term will remain once a medicine reaches the market. In addition, patent litigation adds to uncertainty. *See* e.g. EC Impact Assessment Report, p. 28; D. N. Lakdawalla, Economics of the Pharmaceutical Industry, *Journal of Economic Literature*, Vol. 56, No. 2, 2018, pp. 397–449 ("Lakdawalla, 2018").

8 *See* Lakdawalla, 2018.

9 For example, D. Acemoglu and J. Linn, Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry, *Quarterly Journal of Economics*, Vol. 119, No. 3, 2004, pp. 1049–1090; A. Finkelstein, Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry, *Quarterly Journal of Economics*, Vol. 119, No. 2, 2004, pp. 527–564; P. Dubois, O. de Mouzon, F. S. Morton, and P. Seabright, Market Size and Pharmaceutical Innovation, *RAND Journal of Economics*, Vol. 46, No. 4, 2015, pp. 844–871.

10 *See* M. K. Kyle and A. M. McGahan, Investments in Pharmaceuticals Before and After TRIPS, *Review of Economics and Statistics*, Vol. 94, No. 4, 2012, pp. 1157–1172; E. Budish, B. N. Roin and H. Williams, Do Fixed Patent Terms Distort Innovation? Evidence from Cancer Clinical Trials, *American Economic Review*, Vol. 105, No. 7, 2015, pp. 2044–2085; F. Gaessler and S. Wagner, Patents, Data Exclusivity, and the Development of New Drugs, *Review of Economics and Statistics*, Vol. 104, No. 3, 2022, pp. 571–586.

11 For a study of the effects of orphan drug exclusivity, *see* W. Yin, Market Incentives and Pharmaceutical Innovation, *Journal of Health Economics*, Vol. 27, No. 4, 2008, pp. 1060–1077. For a policy directed at antibiotics, *see* J. J. Darrow and A. S. Kesselheim, Incentivizing Antibiotic Development: Why Isn't the Generating Antibiotic Incentives Now (GAIN) Act Working? *Open Forum Infectious Diseases*, Vol. 7, No. 1, 2020, ofaa001.

12 R. S. Eisenberg, Patents and Regulatory Exclusivity, in *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, P. M. Danzon and S. Nicholson (eds.), Oxford University Press, 2012, ("Danzon and Nicholson, 2012") pp. 167–198/

13 Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC, COM(2023) 192 final, 26 April 2023 ("EC Proposal"), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192, Article 82(1): "[The two-year extension] *shall only be granted to medicinal products if they are released and continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorisation is valid*." Each Member State can waive this requirement, *see* Article 82(2). Note that a failure of a Member State to respond to an applicant's request within sixty days will be considered a waiver of the requirement, *see* Article 82(3).

years.[14] There is some flexibility for small and medium-sized enterprises (SMEs), non-profits, and start-ups,[15] which have three years to fulfil the requirement after obtaining marketing authorization and four years to submit their application.[16]

10. The proposal also includes additional incentives for products that meet an unmet medical need and novel products through the provision of up to two years of additional market exclusivity.[17] Specifically, the innovator is granted (i) six months if the product addresses a previously unmet medical need;[18] (ii) six months if the product contains a new active substance and the firm conducts comparative clinical trials; (iii) one year for new therapeutic indications.[19] The total length of exclusivity can therefore add up to twelve years.[20]

III. The economics of new product launches in the EU

11. The pharmaceutical industry is characterized by significant sunk costs and comparatively low unit production costs. R&D in the pharmaceutical industry is lengthy, risky, and costly. For example, DiMasi et al. (2016) estimate that only 11.8% of product candidates in Phase 1 stage of clinical research successfully obtain marketing authorization. They also find that, on average, Phase 1, Phase 2 and Phase 3 clinical trials take 80.8 months combined. According to their estimates, the expected cost of developing an approved drug can be close to $2.6 billion.[21] Relative to these large R&D expenditures, the cost of producing an additional unit of the pharmaceutical product (i.e., marginal cost) is not significant in many cases.[22]

12. The cost structure of drug development impacts manufacturers' incentives at launch. As the sunk costs are high and marginal costs are low, all else equal, manufacturers facing limited terms of patent protection and market exclusivity are incentivized to launch a product as broadly and early as possible if markets are independent.[23] Launching the product in an additional market (for example, in an additional EU Member State) generates additional sales and profits, which contributes to the recovery of R&D. However, EU-specific factors like reference pricing policies and parallel trade also impact manufacturers' incentives at launch. In the next section, we describe these factors.

1. EU reference pricing and parallel trade create incentives for staggered launches

13. The approval of pharmaceutical products in the EU usually occurs through a centralized process managed by the European Medicines Agency (EMA).[24,25] However, despite authorization decisions at the EU level, pricing is a national competence. ERP and parallel trade link prices across national markets, with implications for firms' incentives to launch pharmaceutical products in additional Member States.

14. ERP is a price-setting mechanism where one country uses the prices set in other countries as a reference for its pricing and reimbursement negotiations. Most EU Member States use a form of ERP as part of their negotiation, but its implementation varies. For example, some EU Member States reference all other Member States, whereas others reference only a subset of countries. Some Member States rely on the lowest price among the reference countries, whereas others rely on an average measure.[26]

15. ERP incentivizes originator firms (i.e. inventors of new pharmaceutical products) to delay launches in jurisdictions where prices are likely to be lower.[27] As discussed above, if prices in different Member States are not linked, a firm has an incentive to launch in additional Member States, even at lower prices, as long as the price is above marginal costs and the fixed costs of launch in the additional Member States are covered. However, ERP links the prices in different Member

14 EC Proposal, Article 81(2)(a), Article 82(2).

15 More specifically, start-ups are defined as "*undertakings that, by the time of granting of a marketing authorisation, have received not more than five centralised marketing authorisations for the undertaking concerned*," *see* Article 81(2)(a)(iii).

16 EC Proposal, Article 81(2)(a), Article 82(2).

17 EC Impact Assessment Report, p. 3.

18 Products that meet unmet medical needs will be defined as a "*medicinal product* (…) *for a life-threatening or seriously debilitating disease with remaining high morbidity or mortality, and the use of the medicinal product results in a meaningful reduction in disease morbidity or mortality*." This definition will be further specified in implementation, under guidance of the European Medicines Agency (EMA). EC Proposal, p. 16.

19 Ibid., Article 81(2).

20 Ibid., p. 16.

21 J. A. DiMasi, H. G. Grabowski, and R. W. Hansen, Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, *Journal of Health Economics*, Vol. 47, 2016, pp. 20–33, at pp. 20–25, Figure 1, Table 4, Figure 2.

22 Marginal costs for complex products, including many biologics, tend to be higher. However, the development costs dwarf the manufacturing costs in general. *See* e.g., Danzon and Nicholson, 2012, pp. 2, 214; Lakdawalla, 2018.

23 M. K. Kyle, Pharmaceutical Price Controls and Entry Strategies, *The Review of Economics and Statistics*, Vol. 89, No. 1, 2007, pp. 88–99 ("Kyle, 2007"), pp. 88–91.

24 The centralized procedure is mandatory for many products, including biologics and those treating important diseases such as cancer and HIV. For other products, firms may opt to apply to national authorities (the decentralized procedure) or request mutual recognition of approved products after receiving authorization from one Member State. EMA, Authorization of Medicines, 3 April 2019, https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines.

25 L. Maini and F. Pammolli, Reference Pricing as a Deterrent to Entry: Evidence from the European Pharmaceutical Market, *American Economic Journal: Microeconomics*, Vol. 15, No. 2, 2023, pp. 345–383 ("Maini and Pammolli, 2023"), pp. 348–349.

26 Ibid., Figure 1.

27 Ibid., p. 345.

States, as the launch price in any Member State can be referenced by others. As a result, launching a new pharmaceutical product in a low-price jurisdiction may have spillover effects on other jurisdictions, and decrease the price in other Member States. Consequently, originator firms choose not to launch, or to delay launch, in the low-price Member States.

16. Similarly, parallel trade undercuts originator firms' incentives to launch new medicines in all markets. Under EU law, intellectual property rights such as patents are "exhausted" once a product is sold in any Member State, and cannot be used to stop imports between EU countries.[28] This prevents manufacturers from using their intellectual property rights to restrict the free movement of goods between Member States, resulting in parallel trade—a process where importers purchase the same pharmaceutical product from a lower-price country, repackage it and sell it in a higher-price country.[29] Parallel trade is profitable if there are large price discrepancies between Member States. This arbitrage between low- and high-price jurisdictions limits the price differential the originator firm can sustain in different Member States, incentivizing the manufacturer to differentiate its products between countries, or in the extreme case, not to launch in low-price markets.[30]

17. Despite the centralized authorization process, there is a significant discrepancy in the products available across EU Member States.[31] Academic research shows that ERP and parallel trade can in part explain this discrepancy. For example, Kyle (2007) shows that new pharmaceutical products are less likely to be launched in certain Member States if ERP and parallel trade are present. Specifically, she finds that a manufacturer is 75% more likely to enter a market if there are no price controls (relative to a market with price controls).[32] Similarly, Maini and Pammolli (2023) find that removing ERP would reduce the delay in new product launches in certain low-income European countries by up to twelve months.[33] Kyle (2011) also shows that firms are likely to engage in non-price strategic behaviour to curb the effects of parallel trade, such as reducing the availability of lower-priced products by not launching in lower-priced countries, or differentiating the products between markets.[34]

28 M. K. Kyle, Strategic Responses to Parallel Trade, *B.E. Journal of Economic Analysis & Policy*, Vol. 11, No. 2, 2011 ("Kyle, 2011"), p. 6.

29 Ibid., pp. 3–4.

30 Ibid., pp. 4–6.

31 M. K. Kyle, The Single Market in Pharmaceuticals, *Rev. Ind. Organ.*, Vol. 55, 2019, pp. 111–135 ("Kyle, 2019"), p. 113.

32 Kyle, 2007, pp. 97–99.

33 Maini and Pammolli, 2023, pp. 345–346.

34 Kyle, 2011, p. 27.

IV. The potential impact of EC's proposed reform to increase access across Member States

1. The proposal is likely to reduce the return to innovation for a significant number of manufacturers

18. Originator firms consider several factors in deciding when to launch their products and in which jurisdictions. Under the current rules, only about 13% of new products are launched (nearly) simultaneously in virtually all Member States.[35] The originators choose to stagger the launches for the remaining products.

19. The proposed policy will not impact the incentives to innovate for originator firms that are incentivized to launch their products in all Member States simultaneously, independent of the reform. They would choose to launch EU-wide regardless of the policy change, which means that even under the proposed policy, their exclusivity period would remain ten years (i.e. eight years of data exclusivity, and two years of market exclusivity).

20. However, the proposed policy has important implications for originator firms that may not have had an incentive to launch the product in all Member States, which has historically accounted for 87% of all pharmaceutical products.[36] These originators fall into two groups—those that:

- May not launch in all Member States despite the proposed reform (Group 1).[37]
- May change their strategy in line with the objectives of the proposed policy, i.e., absent the proposed reform, they would not have launched in all Member States, but after the proposed reform, they would (Group 2).

21. The proposed policy will reduce the incentive to innovate for originator firms in Group 1, as the market exclusivity period for this group will drop from ten to eight years. According to the EC's impact assessment,

35 Between 2016–2024, 12.8% of products with RP exclusivity were launched in at least 20 Member States. *See* EC Impact Assessment Report, Annex II, Table 14.

36 Ibid.

37 In other words, among the originator firms that would not have launched their new pharmaceutical product in all Member States before the reform, some would still choose not to launch their products across the EU after the reform.

originator firms in this group will face 22% lower revenues due to the two-year shortening of the market exclusivity.[38]

22. Similarly, the proposed policy will reduce the incentive to innovate for originator firms in Group 2. This is because even though the length of market exclusivity would remain ten years under the proposed policy, the originator firms in this group would expect to realize lower profits after the proposed policy (if they did not expect lower profits, they would have launched simultaneously in all Member States).

23. Originator firms in Group 2 risk lower profits through ERP and parallel trade because, after the proposed policy, the prices will become linked across more jurisdictions if the launch is more widespread. As we explained above, ERP links the prices in different Member States, and launching a new pharmaceutical product in a low-price jurisdiction may have a spillover impact on other jurisdictions. Similarly, parallel trade limits the price differential the originator firm can sustain in different Member States.

24. Prices in the additional Member States where the product would be launched after the policy change (so that the manufacturer would qualify for the additional two years of market exclusivity) would be lower than the prices in the Member States where the firm would have launched absent the policy change.[39]? Low prices in these Member States would put downward pressure on the price in all Member States, due to ERP and parallel trade. Both factors would reduce the prices in the higher-price jurisdictions and would reduce the expected returns to innovation.

25. Grossman and Lai (2008)[40] argue that linking markets through parallel trade should induce different choices of price controls by trading partners. Because a manufacturer's profits in a high-price country are reduced by arbitrage, it may not launch in a low-price country. Consequently, a low-price Member State should be willing to accept higher prices in order to ensure that the originator will serve the market. We are not aware of empirical evidence that supports this hypothesis.[41] However, the proposed reform increases the negotiating power of low-price countries because serving those markets is a condition of receiving the additional two years of exclusivity. As a result, the price at which the originator is willing to serve the market may be lower, too, with lower profits and incentives for R&D investment.

26. Moreover, after the proposed policy, additional launches would require the originator firm to incur administrative costs associated with a launch in each additional Member State.[42] Such setups are costly and take time.[43] The EC assumes in its impact assessment that these costs can be recouped by sales in these new Member States.[44] However, EC's impact assessment does not account for the effect of launches on average prices in the EU through ERP and parallel trade.

27. The additional costs would outweigh the benefits of launching in additional countries. Specifically, absent the policy change, the originator firm could have chosen to launch the product EU-wide; if it chooses not to, expected revenues must be higher by limiting the number of launch markets. As we have explained, this is due to spillover effects from launching in a low-price country on revenues in other EU Member States.

28. Overall, the proposed policy may reduce the expected returns from innovation for a significant number of manufacturers. This has the effect of reducing investment in new drugs in general, and would adversely impact the competition among pharmaceutical products that can be used to treat similar conditions (e.g., different types of antidepressants, selective serotonin reuptake inhibitors, etc.).[45]

2. The proposal will favour large, incumbent firms

29. Launching a product in a new jurisdiction involves certain setup costs,[46] such as costs associated with conducting pricing and reimbursement negotiations with national authorities, and costs associated with establishing a market presence and distribution channels.[47] Such costs are generally lower for large, incumbent firms with prior experience with launches in the Member State, or that can amortize these costs over many products. In fact, in part due to such fixed costs, smaller innovators commonly enter into agreements where they license

38 EC Impact Assessment Report, Table 4, p. 33.

39 As a matter of economics, if this were not the case, it would have been optimal for the originator to launch in this Member State before the change in regulation.

40 G. M. Grossman and E.L.C. Lai, Parallel Imports and Price Controls, *RAND Journal of Economics*, Vol. 39, No. 2, 2008, pp. 378–402, https://doi.org/10.1111/j.0741-6261.2008.00019.x.

41 Rather, some countries negotiate secret rebates from manufacturers in exchange for a higher public price that reduces arbitrage opportunities in order to ensure that the market is served, but does not result in an increase in net costs for the government.

42 EC Proposal, Article 81(2). The proposal requires originator firms to have launched in all Member States within two years (three for small businesses). Entities which qualify for the longer grace period include SMEs, non-profits, and entities with less than five prior centralized marketing authorizations.

43 Kyle, 2007, p. 91; I. Schofield, EU Pharma Reform Proposes Cuts in Regulatory Protections & Faster Drug Approval Times, *Pink Sheet*, 26 April 2023 ("Pink Sheet, 26.4.2023"), https://pink.pharmaintelligence.informa.com/PS148116/EU-Pharma-Reform-Proposes-Cuts-in-Regulatory-Protections--Faster-Drug-Approval-Times.

44 Specifically, the EC assumes that "*the cost of servicing say 25 EU markets on average rather than say 15 (…) would be cost neutral, with the higher sales volumes in the additional 10 smaller markets offsetting the additional marketing, distribution and other costs associated with smaller / marginal markets*."EC Impact Assessment Report, p. 173, C.4.3.

45 This is because competition between similar pharmaceutical products is characterized by product differentiation. Products that offer greater therapeutic benefits (e.g. greater efficacy or fewer side effects) can hope to be charged at higher prices, achieve greater market share, and have higher returns. As such, as the variety of products that can be used to treat similar conditions increases, competition among these products increases. Z. J. Lu and W. S. Comanor, Strategic Pricing of New Pharmaceuticals, *Review of Economics and Statistics*, Vol. 80, No. 1, 1998, pp. 108–118, at pp. 108–110.

46 Kyle, 2019, pp. 113–120; Kyle, 2007, pp. 2–5.

47 EC Impact Assessment Report, pp. 40–41.

incumbent firms for distributing, marketing, or selling their new products.[48] As part of licensing agreements, parties negotiate how to split the total pie among themselves, where both licensor (small firm) and licensee (incumbent) get a share proportional to their contribution.[49] For the set of Group 2 firms, the proposed policy would increase the returns from launching EU-wide. The incumbent's familiarity with all EU jurisdictions in this situation strengthens the bargaining power of larger firms in licensing negotiations.

3. The proposal will increase the bargaining power of small countries, which may further increase uncertainty

30. The proposed legislation would also increase uncertainty for the originator firms because a failed (or delayed) launch in a single Member State could derail the opportunity for a prolonged exclusivity period. Because the proposal requires the product to be launched in all Member States, this would give each Member State influence over whether the originator will obtain the additional exclusivity period. Each Member State could hold up the two additional years of exclusivity, which increases their bargaining power. This is particularly important for countries that represent a smaller share of profits to a manufacturer, but for the policy change, the manufacturer might choose to delay or forgo launch if the country demands a low price due to the consequences for prices in other markets that result from ERP and parallel trade. However, under the new policy, delaying or forgoing launch means the loss of two years of additional exclusivity, which makes the manufacturer more willing to accept a low price in a small market.

31. In the EU, even before implementing the proposed policy, there is already significant regulatory uncertainty about the length of pricing, reimbursement negotiations and launch process. For example, in 2023, the average turnaround for a pricing and reimbursement application was over 300 days in nine EU countries, and the total lag between approval and launch was even higher.[50] Delays encountered during the pricing and reimbursement process in any country risk pushing the total time to launch beyond two years, increasing the uncertainty of obtaining two additional years of market exclusivity.[51] Higher uncertainty around the length of the exclusivity period implies that, in expectation, originator firms will receive lower returns on their investment.

32. In summary, the goal of increasing access to new pharmaceuticals in all EU countries may be better served by addressing the underlying reasons for launch delays—namely, ERP and parallel trade. Member States could also work to reduce lengthy pricing and reimbursement processes, which do not bring value to manufacturers or patients. To the extent the proposed changes to exclusivity conditions change launch strategies, they also risk harming incentives to innovate. ■

48 H. Grabowski and M. Kyle, Mergers, Acquisitions, and Alliances, in Danzon and Nicholson, 2012, pp. 567–568.

49 A. F. Krattiger et al., *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, Vol. 1, MIHR, Oxford, UK and PIPRA, Davis, California, USA, 2007, p. 815.

50 Maini and Pammolli, 2023, Figure 3. This delay is also noted as a main concern by industry representatives, *see* e.g. G. Naujokaitytė, New pharma rules risk 'sabotaging' life sciences in Europe, says the industry, *Science Business*, 27 April 2023, https://sciencebusiness.net/news/drug-development/new-pharma-rules-risk-sabotaging-life-sciences-europe-says-industry; Pink Sheet, 26.4.2023.

51 The extent of the impact of increased uncertainty will depend on the approval process and whether a product that is launched without reimbursement can still be considered "supplied."Such issues related to practical implementation have not yet been resolved, *see* EC Proposal, Article 82(5), Article 82(6).